

REMARKS

After entry of this amendment, claims 26-44 will be pending. Claims 1-25, which were rejected in the Office action, have been canceled without prejudice or disclaimer. Claims 26-44 are added. Support for the new claims can be found throughout the specification as filed and in the figures, including, *inter alia*, paragraphs [0022], [0035]-[0036], [0056]-[0064] and Figs. 2 and 6. No new matter is added herein.

Applicants thank the Examiner for the courtesy extended during the telephonic interview held July 14, 2008. Applicants confirm that the Interview Summary prepared by the Examiner is a complete and accurate record of the substance of the interview.

Applicants have reviewed the Office action, including the Examiner's remarks and the references cited therein. Applicants submit that the following remarks are fully responsive to the Office action, and that all pending claims are patentable over the cited references.

Rejection Under 35 U.S.C. § 102

The Examiner rejects claims 1, 9, 17-18, 22, and 24-25 under 35 U.S.C. § 102 as anticipated by United States patent no. 6,277,108 to McBroom et al. ("McBroom"). Applicants submit that this rejection is moot in view of the cancellation of the rejected claims.

Rejection Under 35 U.S.C. § 103

The Examiner rejects claims 2-8, 10-16, 19-21, and 23 under 35 U.S.C. § 103 as obvious over McBroom in view of United States patent no. 6,562,049 to Norlander et al. ("Norlander"). Applicants submit that this rejection is moot in view of the cancellation of the rejected claims.

Remarks on Newly Introduced Claims

The Newly Introduced Claims are Novel

To be anticipatory, a single prior art reference must explicitly or inherently teach each and every element of the claimed invention. MPEP § 2131 (citing *Verdegaal Bros.*

v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987)). Applicants respectfully submit that neither of the cited references (McBroom and Norlander) meets this standard with respect to the newly introduced claims.

Claim 26 recites, *inter alia*, “a tearable radiopaque ring ... including at least one radiopaque ring score line along which the radiopaque ring may be broken, wherein the at least one radiopaque ring score line is unfilled.” Claim 35 recites, *inter alia*, “bonding the radiopaque ring to the distal end of the sheath body without introducing polymer or binding agent into the at least one radiopaque ring score line.” Claim 44 recites, *inter alia*, “a contiguous radiopaque ring ... including at least one radiopaque ring score line along which the radiopaque ring may be broken, wherein the at least one radiopaque ring score line is free of polymer and binding agent.” That is, “regardless of whether the score lines 36 are along the interior 26 or exterior 24 of the radiopaque tube 12, the score lines defined in both the radiopaque tube and sheath 10 are hollow, rather than filled in with a polymer or binding agent.” Specification, para. [0036].

McBroom, on the other hand, teaches that “the aperture 410 [of marker band 400] is sized *such that material of the sheath 300 is disposed in the aperture 410 during the thermoforming process.*” McBroom, col. 5:7-10 (emphasis added). *See also* col. 5:33-35 (“In addition, the perforations allow for a mechanical bond to occur between the marker band and the sheath tubing wall when the sheath is thermoformed.”). Thus, rather than teaching that the marker apertures and/or perforations are “unfilled” or “free of polymer and binding agent” as claimed, McBroom explicitly teaches that sheath material is permitted to at least partially fill the apertures and/or perforations during manufacture. McBroom accordingly does not anticipate claims 26, 35, or 44, or claims 27-34 and 36-41, which depend from claims 26 and 35, respectively.

Claim 42 recites, *inter alia*, “breaking the sheath body and the radiopaque ring into two or more pieces *by tearing.*” That is, claim 42 recites that the radiopaque ring may be split or broken by pulling apart (e.g., the application of manual force).

McBroom, on the other hand, teaches that the marker band is slittable—that is, able to be cut through the use of a slit, such as that illustrated in Fig. 2 and described at McBroom, col. 4:15-22. *E.g.*, McBroom, col. 4:52-54 (“In one embodiment, the

marker band 330 comprises a thin marker band which allows for the marker band to be slittable.”); col. 5:43-46 (“[T]he reduced mass of the braided material 620 allows for the amount of slitting force to be reduced, thereby facilitating the slittable nature of both the sheath and the marker band 600”). Applicants respectfully submit that McBroom does not teach that the maker band may be split by tearing (that is, pulling apart with manual force) as in the claimed invention. McBroom accordingly cannot anticipate claim 42 or claim 43, which depends from claim 42.

As the Examiner has previously acknowledged (see Interview Summary of April 23, 2007 Interview), Norlander does not teach a radiopaque ring as claimed. Indeed, to the extent that Norlander teaches a radiopaque metal band, Norlander does not disclose that the band includes “at least one radiopaque ring score line” as recited in the present claims, much less that the band can be broken into pieces. To the contrary, Norlander teaches scoring *only* the sheath. Norlander, col. 6:50-55. Thus, Applicants respectfully submit that Norlander cannot anticipate the newly introduced claims.

The Newly Introduced Claims are Non-Obvious

Though the prior art references need not teach or suggest each and every limitation of a claim for that claim to be obvious, Applicants contend that the differences between the newly introduced claims and the references cited are sufficiently great so as to render the claimed invention non-obvious to one of ordinary skill in the art at the time the invention was made. Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57526, 57527-28 (Oct. 10, 2007) (“[T]he focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on *what such a person would have reasonably expected to have been able to do in view of that knowledge.*”) (emphasis added). In particular, because McBroom and Norlander fail to teach or suggest each and every element of the newly introduced claims, as discussed in detail above, Applicants respectfully submit that one of ordinary skill in the art would not have learned the claimed invention from the combination of McBroom and

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Norlander. Accordingly, Applicants contend that the claimed invention is substantially different from, and therefore not obvious over, the asserted combination of references.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the application is in condition for allowance, and request that all rejections be withdrawn, that all pending claims be allowed, and that the application be passed to issue. If, for any reason, the Examiner finds the application to be in other than condition for allowance, the Examiner is invited to contact the undersigned in an effort to resolve any matter still outstanding before issuing another action.

Applicants have provided for a one month extension of time concurrently herewith. If any further extension of time is deemed necessary for this submission to be considered timely, Applicants hereby petition therefor.

Applicants believe that no fees are due for the additional claims presented. Authorization is hereby granted to charge any fees, including fees for the addition of claims and for any further extensions of time deemed necessary, to Deposit Account No. 50-1129 with reference to Attorney Docket No. 0B-044600US/82410-0054.

Respectfully submitted,

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